



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,689	08/28/2001	Felix Franks	212345US22CONT	8127

31518 7590 06/03/2002
NEIFELD IP LAW, PC
CRYSTAL PLAZA 1, SUITE 1001
2001 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202

EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
----------	--------------

1653

DATE MAILED: 06/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,689

Applicant(s)

FRANKS ET AL.

Examiner

Jeffrey E. Russel

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2001 and 15 February 0202.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 07/479,939.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

Art Unit: 1653

1. The appropriate maintenance fees for U.S. Patent No. 5,098,893 have been paid, and therefore the reissue procedures are available for this patent.
2. This application is objected to under 37 CFR 1.172(a) as lacking the written consent of all assignees owning an undivided interest in the patent. The consent of the assignee must be in compliance with 37 CFR 1.172. See MPEP § 1410.01.

A proper assent of the assignee in compliance with 37 CFR 1.172 and 3.73 is required in reply to this Office action.

While a copy of the consent of the assignee to reissue application 09/270,791 has been submitted, the instant reissue application is a different application, and the rules do not provide any basis for assuming that consent to one reissue application transfers to any or all continuation reissue applications which may be filed.

3. The original patent was actually surrendered during the prosecution of the parent reissue application 09/270,791, and therefore the requirement set forth in 37 CFR 1.178(a) has been satisfied.
4. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,098,893 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

Application/Control Number: 09/939,689
Art Unit: 1653

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

5. The reissue oath/declaration filed with this application is defective because it fails to contain a statement that all errors which are being corrected in the reissue application up to the time of filing of the oath/declaration arose without any deceptive intention on the part of the applicant. See 37 CFR 1.175 and MPEP § 1414.

While copies of two of the reissue oaths/declarations from reissue application 09/270,791 have been submitted, these oaths/declarations necessarily refer to the errors being corrected in that application. The instant continuation reissue application contains claims which are different from those which are present in reissue application 09/270,791, and therefore is presumably correcting different errors than the ones which were corrected in reissue application 09/270,791. Accordingly a new reissue oath-declaration specifically drawn to errors being corrected in this application is required.

Claims 17-44 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

6. Claims 21, 31, 37-39, and 41 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows: There is no original disclosure supporting the exclusion of rennin as is recited in instant claims 21, 31, 37, 39, and 41. Rennin is not mentioned in the disclosure, and silence in the specification is not support for a negative claim limitation.

Art Unit: 1653

See Ex parte Grasselli, 231 USPQ 393, aff'd on reconsideration 231 USPQ 395 (Bd. App. 1983). Accordingly, the negative claim limitations in these claims constitute new matter. Claim 38 recites dissolution in an aqueous solution having a pH of about 7, which embraces dissolution at slightly acidic pHs. However, there is no original disclosure in the specification of dissolution at slightly acidic pHs, the only pHs recited in the sections of the specification cited by Applicants ranging from 7.0 to 7.6. Accordingly, the pH range recited in claim 38 is new matter.

7. Claims 21, 31, 37-39, and 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the exclusion of rennin as is recited in instant claims 21, 31, 37, 39, and 41. Rennin is not mentioned in the disclosure, and silence in the specification is not support for a negative claim limitation. See Ex parte Grasselli, 231 USPQ 393, aff'd on reconsideration 231 USPQ 395 (Bd. App. 1983). Claim 38 recites dissolution in an aqueous solution having a pH of about 7, which embraces dissolution at slightly acidic pHs. However, there is no original disclosure in the specification of dissolution at slightly acidic pHs, the only pHs recited in the sections of the specification cited by Applicants ranging from 7.0 to 7.6. Accordingly, the pH range recited in claim 38 is not supported by the original disclosure of the invention.

8. Claims 17-25, 40, and 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "said step of forming" at claim 17, page 3 of the amendment filed February 15, 2002, line 6, and at

Art Unit: 1653

claim 18, line 1. The only forming mentioned in the independent claim occurs in the dissolving step; however, it is clear that these sections of the claims should be referring to the evaporating step. Claim 40 at line 9 recites that the biologically active material can be an enzyme, and at line 12 recites that the biologically active material can not be an enzyme. Accordingly, it is not clear if enzymes are embraced within the scope of the claim. Claims 42-44 are indefinite for the same reason.

9. Claim 18 is objected to because of the following informalities: At claim 18, lines 1-2, "subatmospheric" should be one word. Appropriate correction is required.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 26-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all of the claims of copending Application No. 09/270,791. Although the conflicting claims are not identical, they are not patentably distinct from each other. The '791 application claims the compositions claimed in instant claims 26-31 (see, e.g., claims 19, 30, and 115), with the exception that the '791 application does not claim a weight ratio of purified biologically active material to carrier substance or a dissolution pH. It would have been obvious to one of ordinary skill in the art to

Art Unit: 1653

determine all operable and optimal weight ratios and dissolution pHs for the claimed compositions of the '791 application because weight ratio is an art-recognized result-effective variable which is routinely determined and optimized in the chemical composition and pharmaceutical arts, and because pH is an art-recognized result-effective variable which is routinely determined and optimized in the chemical solution and pharmaceutical arts. Further, product-by-process claims suggest the processes recited therein. Claims 39-44 are anticipated by numerous compositions claimed in the '791 application, e.g., by claims 19 and 25.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 26-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-71 of copending Application No. 09/939,688. Although the conflicting claims are not identical, they are not patentably distinct from each other. Although the conflicting claims are not identical, they are not patentably distinct from each other. The '688 application claims the compositions claimed in instant claims 26-31 (see, e.g., claims 23, 37, and 63), with the exception that the '688 application does not claim a weight ratio of purified biologically active material to carrier substance or a dissolution pH. It would have been obvious to one of ordinary skill in the art to determine all operable and optimal weight ratios and dissolution pHs for the claimed compositions of the '688 application because weight ratio is an art-recognized result-effective variable which is routinely determined and optimized in the chemical composition and pharmaceutical arts, and because pH is an art-recognized result-effective variable which is routinely determined and optimized in the chemical solution and pharmaceutical arts. Further,

Art Unit: 1653

product-by-process claims suggest the processes recited therein. Claims 39-44 are anticipated by numerous claims in the '688 application, e.g., by claims 47, 54, and 65. Further, a method of making claim suggests claims drawn to the products made by the method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 1653

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In *re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In *re Clinton*, 188 USPQ 365, 367 (CCPA 1976); In *re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

14. Claims 39-43 are rejected under 35 U.S.C. 102(b) as being anticipated by the Townsend et al article. The Townsend et al article teaches lyophilized mixtures comprising RNase (a peptide) and one of Ficoll 70, sucrose, and polyvinylpyrrolidone as protectants of RNase activity. The mixtures are amorphous, which is consistent with their being in a glassy state. For Ficoll 70, for PVP, and for sucrose at pH 10.0 and 6.4, at least 53% of the initial activity is retained after 30 days storage at 45°C, which is consistent with Applicants' claimed retained activity for a longer period of time but at a lower temperature. See, e.g., the Abstract and Figures 4-6. In view of the similarity in the components of the compositions, the compositions' amorphous state, the protectant function of the Ficoll 70, sucrose, and polyvinylpyrrolidone, and the retained activity of the compositions, the compositions of the Townsend et al article are deemed inherently to have the same storage stability and the same T_g claimed by Applicants and are deemed to anticipate the compositions claimed by Applicants. Sufficient evidence of similarity between the compositions of the Townsend et al article and Applicants' claimed

Art Unit: 1653

compositions is deemed to be present to shift the burden to Applicants to show that their claimed compositions are unobviously different than those of the Townsend et al article. Note that even a patentable difference in the process of making does not necessarily impart patentability to product-by-process claims where the product is otherwise anticipated by the prior art. With respect to those claims containing the limitation excluding enzymes, see the above rejection under 35 U.S.C. 112, second paragraph. In any event, Ribonuclease A is not rennin, and Ficoll 70, sucrose, and polyvinylpyrrolidone are not maltotriose.

15. Claims 26, 28-31, and 43 are rejected under 35 U.S.C. 102(e) as Koyama et al. Koyama et al teach stabilized water-soluble dry solid compositions comprising proteinaceous bioactive substances, for example hormones. Aqueous solutions of the proteinaceous bioactive substances are combined with aqueous solutions a polysaccharide composed mainly of maltotriose units at a ratio of polysaccharide:protein of preferably 1 to 10,000. The weight ratio of the polysaccharide to the substance is at least 0.5, preferably from 1.0 to 10000. The combined solutions are then dried, either by conventional procedures at reduced pressure and a temperature below 30°C, or else by freeze-drying. In one series of examples, greater than 90% of activity is retained after storage at 37°C for one month, which is consistent with Applicants' requirement for at least 53% retained activity after storage for 8 weeks at 25°C. The dry solid can be formed into a tablet. See, e.g., the Abstract; column 2, lines 10-24 and 38-66; Experiment 3; and the Examples. In view of the similarity in the components of the compositions and the retained activity of the compositions, the compositions of Koyama et al are deemed inherently to have the same storage stability, and T_g claimed by Applicants and are deemed to anticipate the compositions claimed by Applicants. Sufficient evidence of similarity between the compositions of Koyama et al and

Art Unit: 1653

Applicants' claimed compositions is deemed to be present to shift the burden to Applicants to show that their claimed compositions are unobviously different than those of Koyama et al. Note that even a patentable difference in the process of making does not necessarily impart patentability to product-by-process claims where the product is otherwise anticipated by the prior art.

16. Claims 32-34, 36, and 37 are rejected under 35 U.S.C. 103(a) as being obvious over Koyama et al as applied against claims 26, 28-31, and 43 above, and further in view of Applicants' admission of the prior art at column 1, lines 59-62; column 4, lines 57 - 66; and column 5, lines 3-8. Koyama et al do not teach any examples in which conventional drying procedures at reduced pressure and a temperature below 30°C are used. However, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to form the dried compositions of Koyama et al using conventional drying procedures at reduced pressure and at a temperature below 30°C because as admitted by Koyama et al, such drying procedures are conventional and are suitable for producing Koyama et al's desired products, and because as admitted by Applicants at column 1, lines 59-62, of the application, freeze-drying is costly in capital and energy and is irreproducible. Regardless of the method used to produce the dried compositions of Koyama et al, the dried compositions of Koyama et al would have been expected to have a T_g greater than 20°C because as admitted by Applicants at column 4, lines 59-60, the T_g for maltotriose is 76°C and as admitted by Applicants at column 5, lines 3-8, the T_g for water-soluble or water-swellaable synthetic polymers is a function of molecular weight.

Accordingly, the T_g for Koyama et al's polysaccharide composed mainly of maltotriose units would have been expected to be even higher than the 76°C for a maltotriose monomer. The T_g

Art Unit: 1653

for Koyama et al's proteinaceous bioactive substances would also have been expected to be relatively high because the proteins are also water-soluble polymers of relatively high molecular weight. Even if Koyama et al's dried compositions were to contain several percent residual water after drying, in view of Applicants' admitted rule-of-thumb at column 4, lines 63-65, of an approximately 6°C decrease in T_g for each percent of moisture added, the dried compositions would still have a T_g greater than 20°C in view of the relatively high T_g of the major components.

17. Claims 17, 19, 25, 40, and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by the Shah dissertation. The Shah dissertation teaches combining rennin, an enzyme, with preservatives such as gelatin (a synthetic polymer as well as a water soluble and a water-swellaable synthetic polymer), dextrin, hydroxyethyl starch, and sucrose (a disaccharide) in an aqueous solution and spray-drying the aqueous solution. Spray drier residence time is about 15 seconds. The air temperature at the bottom (exit) of the drier is 160°F (71°C). The spray-drying results in a dried product having from 0.5% to 3.5% water. As high as 93% of activity is retained after storage at 37°C for four months, which exceeds Applicants' requirement for at least 53% retained activity after storage for 8 weeks at 25°C. See, e.g., page 42, lines 1-9; pages 98-99; page 169, lines 1-11; and page 172, lines 3-7. Spray drying occurs without sublimation of water, without freezing of water, and without cooling below 20°C, and results in evaporation of liquid water from the sprayed droplets of the aqueous solution to be dried. In view of the similarity in the components of the compositions, the drying procedures, the water contents of the dried compositions, and the retained activity of the dried compositions, the compositions of the Shah dissertation are deemed inherently to have the same T_g and to be in the same glassy

state claimed by Applicants and are deemed to anticipate the compositions claimed by Applicants. Sufficient evidence of similarity between the dried compositions of the Shah dissertation and Applicants' claimed compositions is deemed to be present to shift the burden to Applicants to show that their claimed compositions are unobviously different than those of the Shah dissertation. Note that even a patentable difference in the process of making does not necessarily impart patentability to product-by-process claims where the product is otherwise anticipated by the prior art. With respect to those claims containing the limitation excluding enzymes, see the above rejection under 35 U.S.C. 112, second paragraph.

18. Claims 17, 19, 25, 40, and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by the Shah dissertation as applied against claims 17, 19, 25, 40, and 42-44 above, and further in view of Applicants' admission of the prior art at column 4, line 66, and column 5, lines 3-8; and further in view of Forsthoff. The dried compositions of the Shah dissertation would have been expected to have a T_g greater than 20°C because as admitted by Applicants at column 4, line 66, the T_g for sucrose is 55°C and as admitted by Applicants at column 5, lines 3-8, the T_g for water-soluble or water-swellaable synthetic polymers is a function of molecular weight. Accordingly, the T_g for the Shah dissertation's dried compositions comprising sucrose and minimal amounts of water would have been expected to be about 55°C. The T_g for the Shah dissertation's dried compositions comprising gelatin, dextrin, or hydroxyethyl starch and minimal amounts of water would also have been expected to be relatively high because the preservatives are water-soluble polymers of relatively high molecular weight. Forsthoff shows that rennin (i.e. rennet or chymosin) is pharmacologically active (see, e.g., the Abstract).

Art Unit: 1653

19. Claims 26-29, 32-35, and 38 are rejected under 35 U.S.C. 103(a) as being obvious over the Shah dissertation. Application of the Shah dissertation is the same as in the above rejections of claims 17, 19, 25, 40, and 42-44. The Shah dissertation does not teach Applicants' claimed weight ratios of biologically active material to carrier substance or Applicants' claimed dissolution pHs. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal weight ratios of the rennin and the preservatives and all operable and optimal dissolution pHs in the Shah dissertation because weight ratio and pH are art-recognized result-effective variables which are routinely determined and optimized in the chemical arts.

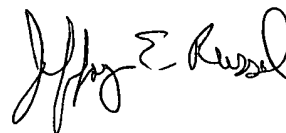
20. Claims 18 and 20-24 are novel and unobvious over the prior art of record or any combination thereof. With respect to claim 18, the prior art of record does not teach drying a composition comprising the recited purified biologically active materials to a water content of no more than 4 wt. % by evaporating water at subatmospheric pressure while heating to a temperature of at 30-80°C. Note that the Townsend et al article freeze-dries rather than heats in order to dry its compositions, that Koyama et al do not teach or suggest a water content of no more than 4% by weight, and that the Shah dissertation does not teach or suggest subatmospheric pressures. With respect to claims 20-24, the prior art of record does not teach drying a composition comprising the recited purified biologically active materials to a water content of no more than 4 wt. % by evaporating liquid water at a temperature not exceeding 80°C. Note that the Townsend et al article freeze-dries rather than heats in order to dry its compositions, that Koyama et al do not teach or suggest a water content of no more than 4% by weight, and that the Shah dissertation does not teach or suggest the recited purified biologically active materials.

Art Unit: 1653

21. Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1653

JRussel

May 24, 2002